DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 20, 2014

Straumann USA, LLC
Mr. Christopher Klaczyk
Director of Regulatory Affairs and Clinical Research
60 Minuteman Road
Andover, MA 01810

Re: K140878
Trade/Device Name: Straumann® Bone Level Tapered Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: July 22, 2014
Received: July 23, 2014

Dear Mr. Klaczyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## 4. Indications For Use

510(k) Number (if known): K140878

Device Name: Straumann® Bone Level Tapered Implant
Roxolid SLActive

Indications for Use:

Straumann® dental implants are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments).

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number (if known): K140878

Device Name: Straumann® Bone Level Tapered Implant
Titanium SLA

Indications for Use:

Straumann® dental implants are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments). In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.

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| Prescription Use ____X___<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____<br>(21 CFR 801 Subpart C) |

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Concurrence of CDRH, Office of Device Evaluation (ODE)

## 5. 510(k) Summary

**Submitter:** Straumann USA, LLC (on behalf of Institut Straumann AG)
60 Minuteman Road
Andover, MA 01810
Registration No.: 1222315 Owner/Operator No.: 9005052

**Contact Person:** Christopher Klaczyk
Director of Regulatory Affairs and Clinical Research

**Date Prepared:** April 22, 2014

**Product Code(s):** DZE (21 CFR 872.3640)

**Device Class:** II (21 CFR 872.3640)

**Classification Panel:** Dental

**Classification Name:** Endosseous dental implant (21 CFR 872.3640)

**Proprietary Name:** Straumann® Bone Level Tapered Implants

**Predicate Device(s):**

- Straumann P.004 Implants – Ti Bone Level implants (K062129)
- Straumann Dental Implant System – 3.3mm NC TiZr Bone Level implants (K083550)
- Straumann Dental Implant System – 4.1& 4.8mm TiZr Bone Level implants (K121131)
- Straumann Dental Implant System (K123784)
- Straumann Dental Implant System (K130222)
- Straumann Tissue Level Titanium Implants (K983742)
- Straumann NC Anatomic Abutment (K071357)
- Straumann NC Cares Abutments (K081005)
- Nobel Biocare, NobelSpeedy (K050406)
- Nobel Biocare, NobelActive (K071370)

**Device Description:** The subject devices represent a line extension of the previously cleared Bone Level implants of the Straumann Dental Implant System (K062129, K083550 and K121131). The subject devices have the same diameters (3.3, 4.1 and 4.8 mm), the same implant-to-abutment interfaces (NC, RC) the same lengths (8 to 14 mm), the same materials (CP Ti and Ti-13Zr) and the same surface finishes (SLA, SLActive) as the identified predicate devices. The subject devices differ in that the apical aspect of the implants incorporate a tapering thread form, the

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|---|---|
| | apical aspect of the implants incorporate three cutting flutes, an additional length of 16mm and the transfer piece is of a new design. |
| **Intended Use: Roxolid SLActive** | Straumann® dental implants are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments). |
| **Intended Use: Titanium SLA** | Straumann® dental implants are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments). In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases. |
| **Materials:** | Versions of the subject devices will be produced from either grade 4 commercially pure titanium conforming with ISO 5832-2 or a titanium-13zirconium alloy, trade named Roxolid®, as previously reviewed and cleared to market per premarket notification submissions K083550 and K121131 for the predicate devices, as well as K081419, K111357 and K122855.<br><br>The transfer piece is produced from titanium-6aluminum-7niobium alloy (TAN) conforming with ISO 5832-11. This is the same material as for the predicate transfer pieces cleared to market per premarket notification submissions K062129, K083550 and K121131. |

**Technological Characteristics:**

The subject devices have the same Indications For Use, diameters (3.3, 4.1 and 4.8 mm), lengths (8 to 14 mm), implant-to-abutment connections (NC, RC), materials (CP Ti and Ti-13Zr), surface finishes (SLA, SLActive), coronal thread form, packaging, sterilization process and dynamic fatigue performance as the identified Bone Level predicate devices (see comparison below).

The subject devices have an equivalent apical tapered thread form with cutting flutes as the identified Nobel predicates.

| Feature | Predicate Devices<br>Bone Level Implants<br>(K062129, K083550, K121131) | Subject Devices<br>Bone Level Tapered Implants |
|---|---|---|
| **Implant-to-Abutment Connection** | Narrow CrossFit® (NC)<br>Regular CrossFit® (RC) | Narrow CrossFit® (NC)<br>Regular CrossFit® (RC) |
| **Implant Diameter** | Ø3.3mm, Ø4.1mm, Ø4.8mm | Ø3.3mm, Ø4.1mm, Ø4.8mm |
| **Implant Length** | 8, 10, 12, 14mm | 8, 10, 12, 14, 16mm |
| **Coronal Thread Form** | Constant major and minor thread diameters (i.e., parallel wall)<br>0.8mm thread pitch | Constant major and minor thread diameters (i.e., parallel wall)<br>0.8mm thread pitch |
| **Apical Thread Form** | Constant major and minor thread diameters (i.e., parallel wall)<br>0.8mm thread pitch | Angled major and minor thread diameters (i.e., tapered wall), with the major and minor diameters have differing angles such that the depth increases toward the apical end of the implant and the addition of cutting flutes.<br>0.8mm thread pitch |
| **Surface Finish** | SLA, SLActive | SLA, SLActive |
| **Transfer Piece** | Thread mount transfer piece<br>Intended to support the implant while in the primary package, to aid in the removal of the implant from the primary package, and to aid in placement of the implant into the osteotomy site. | Snap fit mount Loxim™ transfer piece<br>Intended to support the implant while in the primary package, to aid in the removal of the implant from the primary package, and to aid in placement of the implant into the osteotomy site. |
| **Material** | Commercially pure grade 4 titanium & Titaniun-13Zirconium alloy (Roxolid®) | Commercially pure grade 4 titanium & Titaniun-13Zirconium alloy (Roxolid®) |
| **Primary Package SLActive** | Vial of styrene-butadiene block copolymer (Styrolux), vial cap of LDPE and an implant holder of Grilamid TR70 polyamide.<br>As delivered, the package is filled with aqueous NaCl solution. | Vial of styrene-butadiene block copolymer (Styrolux), vial cap of LDPE and an implant holder of Grilamid TR70 polyamide.<br>As delivered, the package is filled with aqueous NaCl solution. |
| **Sterilization** | Gamma Irradiation, 25 kGy minimum<br>Validated per ISO 11137-1 and ISO 11137-2 to an SAL of $1 \times 10^{-6}$ | Gamma Irradiation, 25 kGy minimum<br>Validated per ISO 11137-1 and ISO 11137-2 to an SAL of $1 \times 10^{-6}$ |

**Performance Data:** Per *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments* dated May 12, 2004, the substantial equivalence of the subject device(s) are satisfactorily addressed via bench studies. Dynamic fatigue test data consistent with FDA guidance and ISO 14801 have been referenced in support of this submission. This data shows that the subjects devices provide performance that is substantially equivalent to the identified predicate devices.

**Conclusions:** Based upon our assessment of the design and applicable performance data, the subject devices have been determined to be substantially equivalent to the identified predicate devices.